Paul Minicozzi, PhD
Senior Director, Scientific Affairs

CURRENT JOB RESPONSIBILITIES

2005 - Current Wyeth Research Collegeville, PA, USA

SENIOR DIRECTOR, SCIENTIFIC AFFAIRS

For most Legacy Products, responsible for:

- Acting as Medical/Scientific Monitor
- Reviewing and approving all documents, Periodic Reports and literature concerning these products prepared by Global Safety Surveillance Division
- Scientific information and review of labeling (including Core Data Sheets and SmPC) updates for Caribbean affiliates
- Assisting Drug Information Division with responses to inquiries

For all Wyeth Products, responsible for:

- Preparing appropriate health hazard evaluation as during product quality issues (potential recall) and acting as Medical Affairs delegate to the Product Quality Review Management Committee
- Directing all activities concerning product shortages including determining medical necessity, allocation of product and communication plan
- Providing input regarding medical/scientific appropriateness of educational grants and substitute Medical Affairs representative to Independent Education Grant Review Committee
- Acting as Medical Affairs representative on the Healthcare Systems Copy Clearance Committee (HCS-CCC) and responsible for accurate review of information and final approval
- Acting as Medical Affairs representative on the Wyeth Corporate Occupational Exposure Guidelines (OEG) Committee that sets limits on exposure of drug received by workers in the manufacture of our pharmaceuticals
- Deciding whether product is life saving/medically important when a product is being considered for discontinuation, whether such action will create health hazard and/or undue hardship to healthcare professionals and preparing appropriate report (Discontinuation Assessment).
- Providing Medical Affairs input to resolution of any questions pertaining to which package inserts and to what extent these should be placed in the PDR and its supplements
- Assisting other departments in coordinating efforts related to emergency preparedness
- Directing activities for the writing of policies or guidances pertaining to Scientific Affairs functions

PROFESSIONAL EXPERIENCE

1992 to 2004 Wyeth Pharmaceuticals Collegeville, PA, USA
DIRECTOR, SCIENTIFIC AFFAIRS

For the more than 30 products in the Diversified Products/Generics portfolios, responsible for:

- Acting as Medical/Scientific Monitor
- Reviewing all initial documents and Periodic Reports prepared by Global Safety Surveillence Division and literature concerning these products to evaluate whether an adverse reaction occurred and/or a labeling change may be needed
- Assisting Drug Information Division with responses to inquiries
- Monitoring any Phase IV studies
- Overseeing Medical Affairs review and signoff on promotional materials

For all Wyeth Pharmaceutical products, responsible for:

- Directing medical Affairs involvement in presentations made for formulary acceptance where a Medical Science Liaison is not assigned
- Acting as expert witness for product claims
- Coordinating compassionate use program when needed
- Directing, coordinating and/or implementing special projects of a scientific nature related to the Medical Affairs Department
- Medical Affairs representation on Copy Clearance Committee for promotional and educational materials for diversified products
- Assisting Wyeth's Government Relations in coordinating efforts within the Medical, Marketing and Sales Departments regarding federal and state bills that affect company interests
- Providing scientific review of information from Business Development Department
- concerning the acquisition, development or licensing of a compound
- Coordinating indigent patient program when
- Acting as liaison with in-house attorneys and local counsel for the preparation of interrogatory responses and requests for admission, and their education about the pharmacology of pertinent drugs

1992 Wyeth Pharmaceuticals Radnor, PA, USA
ASSOCIATE DIRECTOR, SCIENTIFIC AFFAIRS

Responsible for:

- Completing special projects in the Medical Affairs Department involving interaction with Marketing, Institutional Sales, Legal and Government Relations Departments
- Providing initial review for promotional materials for injectables and Tubex system
- Assisting Drug Information personnel with responses for institutional product line

1990-1992 Wyeth Pharmaceuticals Radnor, PA, USA
ASSOCIATE DIRECTOR, DRUG INFORMATION

Responsible for:

- Providing drug information for Elkins-Sinn and selected Wyeth-Ayerst and A.H. Robins products
- Receiving adverse reaction reports
- Recommending and coordinating studies to be performed by the Research and Development Department in response to customer requests

- Preparing technical bulletins for distribution by the hospital sales force
- Review of all labeling for Elkins-Sinn products
- Training of hospital sales representatives regarding injectable products

1987-1990 Elkins-Sinn, Inc Cherry Hill, NJ, USA
ASSOCIATE DIRECTOR, PROFESSIONAL SERVICES

Responsible for:

- Providing all drug information for more than 60 generic injectable products
- Resolving all product quality complaints
- Directing all adverse reaction reports received by company
- Acting as legal intermediary between A. H. Robins legal staff and Elkins-Sinn
- Coordinating any potential claims against Elkins-Sinn with the Claims Department
- at A. H. Robins
- Approving final labeling
- Training of sales representatives
- Acting as Recall Coordinator during the market withdrawal of product
- Writing and/or updating department SOP's

1986-1987 Elkins-Sinn, Inc Cherry Hill, NJ, USA
COORDINATOR, PROFESSIONAL SERVICES

Responsible for:

- Answering customer and internal technical questions
- Answering customer product quality complaints
- Maintaining and updating complaint files and logs
- Advising management of any trends based upon product quality complaints
- Preparing technical bulletins for distribution to sales force and customers
- Researching literature relative to drug information for customers
- Reviewing advertising, scientific information, labeling and package insert revisions
- Monitoring adverse reaction reports and assisting Regulatory Affairs in formulating
- appropriate responses

EDUCATION

1977–1983 TEMPLE UNIVERSITY SCHOOL OF PHARMACY Philadelphia, Pa
Ph.D. Degree/Pharmacology
Rho Chi

1975–1977 PHILADELPHIA COLLEGE OF PHARMACY & SCIENCE Philadelphia, Pa
MSc/Pharmacology

1968–1973 PHILADELPHIA COLLEGE OF PHARMACY & SCIENCE Philadelphia, Pa
BSc/Pharmacy
Dean's List

PROFESSIONAL LICENCES

State of Pennsylvania – License to Practice Pharmacy

PROFESSIONAL MEMBERSHIPS

None

ADDITIONAL PROFESSIONAL ACTIVITIES

None

AWARDS RECEIVED

None

PERSONAL INFORMATION (ADDRESS, PHONE NUMBERS AND E-MAIL)

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Signature: _____

Date: _____